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TO: Commissioner Christine C. Ferguson and Members of the Public Health Council

THROUGH: Paul Dreyer, Ph.D. Interim Associate Commissioner, Center for Health Quality Assurance and Control

FROM: Grant Carrow, Ph.D., Director
Drug Control Program

DATE: December 16, 2003

RE: Request for Final Promulgation of Amendments to 105 CMR 721.000: Standards for Prescription Format and Security in Massachusetts

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Introduction

The purpose of this memorandum is to request the Public Health Council's approval for final promulgation of amendments to 105 CMR 721.000: Standards for Prescription Format and Security in Massachusetts. The proposed regulations would establish standards for secure electronic transmission, authentication and validation of signed, written prescriptions for Schedule VI controlled substances (legend pharmaceuticals). The proposed regulations would also codify current state and federal standards for authentication and validation of unsecured, electronic transmission of prescriptions for controlled substances in Schedules III through V (narcotics and stimulants) as well as Schedule VI.

A public hearing was held on November 25, 2003 to solicit input on the proposed regulations and a public comment period was held open until December 15, 2003. A full technical overview of the background and strategy of the regulations was presented in the informational memorandum of October 28, 2003. The proposed regulation is provided as Attachment A.

Purpose

The regulations proposed here set forth standards for content, format and security for electronic prescriptions that are the electronic equivalent of those that apply to signed, paper-based written prescriptions. The proposed regulations are technology neutral, that is, they avoid specifying a particular technology, in order to allow application of emerging and future

technologies. The regulations are designed to enable this new technology while preventing or minimizing the risks of prescription forgery or other fraud, medication errors and breaches of confidentiality. This would be achieved by requiring security measures that ensure that electronic, written prescriptions are no less secure or legal than original, signed, paper-based written prescriptions. The regulations should result in the upholding of and improvement upon existing protections for patient health and individual safety.

Public Hearing and Comment

Testimony provided at the public hearing and during the public comment period was supportive of the intent of the proposed regulations.

One technical concern raised by a number of those testifying and commenting was the proposed format requirement for use of a digitized image of an indication of “no substitution” for the subset of electronic prescriptions for which the prescriber would require override of mandatory generic interchange. However, the statutory language that necessitated this approach has now been amended, with the recent passage and signing of S. 2076, to render the requirements technology neutral. Consequently, we have similarly amended the proposed regulations to allow for a fully electronic and technology neutral indication of “no substitution”.

Another technical concern raised in testimony and comment was that public key infrastructure (PKI) and digital signature technology was likely the only technology available today that could meet the standards as written. Industry representatives indicated that while the level of security inherent in PKI was one to which the industry should aspire, an infrastructure standard for PKI and digital signatures is not available today and design and adoption of such a standard would be both prohibitively time consuming and costly. Moreover, industry representatives felt that they are already meeting high standards of security with innovative uses of existing technologies, including combinations of security measures such as encryption, multi-factor authentication, time and date stamping and audit trails. In addition to technological security measures, physical and administrative security measures can be utilized to ensure a high level of security for electronic prescriptions.

It was not the intent of the Department to set standards that would require use of PKI and digitial signatures to the exclusion of other promising technologies. We believe that the level of security that can be achieved today can approach the level inherent in PKI and should be sufficient for electronic prescriptions for Schedule VI substances. We have clarified the regulations accordingly. Moreover, we have designed the regulations to be adaptable to emerging and future technologies. As the digital security industry matures and increasingly sophisticated security measures become available, the regulations would require such measures to be applied to electronic prescriptions.

It will be important for all parties involved in the electronic transmission of prescription information to cooperate in designing systems with the appropriate technological, physical and administrative security controls. The Department will work with industry and interested parties to develop regulatory guidance for electronic prescriptions and will consider amending any policies or regulations as the industry matures or as otherwise necessary.

Expected Outcome

With the regulatory standards proposed here in place, we would expect use of existing technologies to enable a secure electronic prescription for a legend pharmaceutical to be

generated and electronically signed in confidence by the prescriber, transmitted in a secure manner over a network and received only by the pharmacy of the patient's choosing in an unchanged format that can be read, validated and stored in a retrievable and readable form only by the pharmacy.

Use of electronic prescriptions would be voluntary on the part of prescribers, pharmacists and patients. The regulations would provide an additional option for Schedule VI prescriptions and all other forms of transmission in place today would continue to be permitted. These other forms, including paper-based written prescriptions, oral prescriptions, unsecured electronic prescriptions (e.g., faxes) and prescriptions for federally controlled substances in Schedules II through V would continue to be handled as they are today. Recordkeeping requirements that apply to prescriptions today would apply to secure electronic prescriptions, except that records for secure electronic prescriptions could be stored electronically rather than on paper. The proposed regulations would automatically adopt expected US Drug Enforcement Administration standards for secure Schedule II through V electronic prescriptions once those are promulgated.

Under the proposed regulations, current enforcement mechanisms, including requirements for controlled substances registrations, pharmacy licensing and inspections, recordkeeping and complaint investigations, would apply to electronic prescriptions as they do to all other prescriptions today.

Conclusion

Department staff believe that the content, format and security requirements in the proposed regulations would enable electronic prescriptions that incorporate necessary and appropriate safeguards and controls. The regulations would create the conditions under which the potential for electronic prescriptions to contribute to improvements in public health and safety can be fully realized in the Commonwealth.

ATTACHMENT A

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 721.000: STANDARDS FOR PRESCRIPTION FORMAT AND SECURITY IN MASSACHUSETTS

Section
721.001: Purpose
721.002: Authority
721.003: Citation
721.004: Scope and Application
721.010: Definitions
721.020: Prescription Formats
721.030: Security Standards for Prescriptions
721.040: Invalid Prescriptions
721.050: Prescribing More than One Product

721.001: Purpose

The purpose of 105 CMR 721.000 is to specify the requirements for prescription format and security in Massachusetts.

721.002: Authority

105 CMR 721.000 is adopted pursuant to M.G.L. c. 30A, § 2; c. 94C, § 6; c. 111, § 3; and c. 112, § 12D.

721.003: Citation

105 CMR 721.000 shall be known as 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts.*

721.004: Scope and Application

105 CMR 721.000 establishes the standards for format and security in the Commonwealth that all prescriptions issued by practitioners or reduced to writing by pharmacists must meet in order to comply with M.G.L. c. 112, § 12D and M.G.L. c. 94C.

721.010: Definitions

The terms used herein shall have the meanings set forth below. Terms defined in M.G.L. c. 112, § 12D and c. 94C, § 1 and not defined herein shall have the meanings set forth therein when used in 105 CMR 721.000, unless the context clearly requires a different interpretation.

Authentication means that the identities of the parties sending and receiving prescription data are duly verified.

Confidentiality means that only authorized persons have access to prescription data.

Content integrity means that prescription data have not been altered or compromised in transmission.

Drug product means the final dosage form of a drug that is marketed under a brand or generic name.

Electronic signature means an electronic sound, symbol or process attached to or logically associated with a prescription record and executed or adopted by a practitioner with the intent to sign said prescription record.

Technical non-repudiation means that parties to the generation, transmission, receipt or storage of an electronic prescription cannot reasonably deny having participated in said activities.

721.020: Prescription Formats

(A) Every prescription written in the Commonwealth must be in a prescription format that conforms to the following requirements:
  (1) a prescription must permit the practitioner to instruct the pharmacist to dispense a brand name drug product by indicating “no substitution”, provided that:
    (a) the indication of "no substitution" is not the default indication;
    (b) the prescription indicates that "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law"; and
    (c) the indication of “no substitution” is a unique element in the prescription and shall not be satisfied by use of any other element, including the signature;
  (2) if the prescription is paper-based, including but not limited to a prescription that is transmitted via facsimile or similar technology or reduced to writing by a pharmacist, the prescription must be on a form that contains a signature line for the practitioner's signature on the lower portion of the form. Hospital and clinic prescription forms shall contain a line directly below the signature line for the practitioner to print or type his/her name. Below the signature line, or in the case of hospital and clinic prescription forms, below the line provided for the practitioner to print or type his/her name, there shall be a space in which the practitioner may indicate "no substitution". Below this space shall be printed the words "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law";
  (3) if the prescription is transmitted electronically, the practitioner shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form;
  (4) the name and address of the practitioner shall be clearly indicated on the prescription. A hospital or clinic prescription shall have the name and address of the hospital or clinic clearly indicated on the prescription;
  (5) the prescription shall contain the following information:
    (a) the registration number of the practitioner;
    (b) date of issuance of the prescription;
    (c) name, dosage, and strength per dosage unit of the controlled substance prescribed, and the quantity of dosage units;
    (d) name and address of the patient, except in a veterinary prescription;
    (e) directions for use, including any cautionary statements required; and
    (f) a statement indicating the number of times to be refilled.
(B) Prescriptions for certified nurse midwifes, nurse practitioners, psychiatric nurses and physician assistants shall also contain the name of the supervising physician.

721.030: Security Standards for Prescriptions

(A) A prescription may be transmitted electronically provided that:
  (1) if said prescription is for a controlled substance in Schedules II through V, it is validated and authenticated in accordance with M.G.L. c. 94C and applicable Department regulations, if any, and 21 CFR 1306 and other applicable federal regulations;
  (2) if said prescription is for a controlled substance in Schedule VI it is validated and authenticated in accordance with requirements in M.G.L. c.94C and applicable Department regulations for oral prescriptions or by utilizing a system that includes:
    (a) a combination of technical security measures, such as, but not necessarily limited to, those listed in Security Standards for the Protection of Electronic Protected Health Information (HIPAA), 45 CFR Part 164, Subpart C, § 164.312, as most recently amended, to ensure a reasonable and appropriate level of:
      (i) practitioner and dispenser authentication;
      (ii) technical non-repudiation;
      (iii) content integrity; and
      (iv) confidentiality;
    (b) an electronic signature that is:

(i) unique to an identified practitioner;
(ii) originated solely by and under the ultimate control of the practitioner; and
(iii) capable of verification; and

(c) reasonable and appropriate security measures to invalidate a prescription if either the electronic signature or the prescription record to which it is attached or logically associated is altered or compromised; and

(3) said prescription meets any other generally applicable requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) and related regulations.

(B) An electronic signature that meets the requirements of 105 CMR 721.030 shall have the full force and effect of a handwritten signature on a paper-based written prescription.

(C) A paper-based written prescription must be written and signed by the practitioner in accordance with M.G.L. c. 94C, §23 and 105 CMR 721.000.

721.040: Invalid Prescriptions

(A) A prescription in a format that does not conform to 105 CMR 721.000 is invalid and shall not be filled.

(B) A prescription that does not meet the security requirements of 105 CMR 721.000 is invalid and shall not be filled.

721.050: Prescribing More Than One Drug Product

Practitioners who wish to prescribe more than one drug product, with the same or different dispensing instructions, shall place each prescription on a separate prescription form or record. More than one drug product may be prescribed in the hospital setting on a single form or record provided, however, that the prescription provides clear directions for use and interchange of each drug product.